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09/939,011	08/24/2001	James Benn	GEN-007ACP	3415

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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,011	BENN ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 August 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9&10/02* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in papers filed 18 April 2003 is acknowledged. The traversal is on the grounds(s) that restriction is only required when the invention are independent and distinct and that the subject matter of the two groups are not independent and distinct because they represent a single inventive concept and because they are linked by a single searchable unifying aspect.

The arguments are not found persuasive because dependent inventions may be properly restricted if they are distinct. As discussed in MPEP 803, one of the two criteria for requirement of restriction is that the "inventions must be independent (see MPEP 802.01, 806.04, 808.01) or distinct as claimed". Accordingly, the demonstration of distinctness of the inventions is sufficient grounds for restriction. As stated in MPEP 802.01 "(t)he law has long been established that dependent inventions (frequently termed related inventions) such as those used for illustration above may be properly divided if they are, in fact "distinct" inventions, even though dependent".

Applicants further argues that the groups are linked by a single searchable unifying aspect and as such it would not be undue burden to examine the claims of groups I and II. However, it is maintained that undue burden would be required to examine the claims of group II along with claims of group I as evidenced by the fact that the claims of groups I and II have acquired a separate status in the art as recognized by their different classifications as recognized by their divergent subject matter and because a search of the subject matter of invention I is not co-extensive with a search of invention II. Specifically, a search of the subject matter of group I would encompass a search of apparatus art including e.g. plates, sample chambers, separation membranes, optical windows, syringe docking and sealing

means. In contrast, a search of the subject matter of group II would encompass a search of DNA detection art including e.g. filtration, hybridization, primers, polymerase, nucleotide incorporation, label detection and temporal analysis. As such, a search of the subject matter of invention I would not be co-extensive with a search of the subject matter of invention II.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 8-13, 16, 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999).

Regarding Claim 1, Lipshutz et al disclose a flat plate nucleotide detection cell, comprising: an upper flat plate, a sample chamber formed along a bottom surface of said upper flat plate for holding a sample (i.e. planar member); a membrane provided along a portion of said sample chamber for separating a sample in the sample chamber (Column 17, lines 28-49),

and an optical window provided in said upper flat plate (Column 14, line 12-Column 15, line 28 and Column 19, lines 20-29), said optical window for permitting light to pass between the sample chamber and a detector for monitoring the sample chamber (Column 4, lines 16-21).

Lipshutz et al teach the device comprises a membrane along a portion of the sample chamber (Column 17, lines 28-49). The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). The recitation for "separating a sample in the sample chamber" describes an intended use for the membrane but does not distinguish over the structure teaching of Lipshutz et al. Therefore, Lipshutz et al teach the detection cell as claimed.

Regarding Claim 8, Lipshutz et al disclose the detection cell of claim 1, further comprising a vent hole in fluid communication with the sample chamber providing a vent for the sample chamber (Column 17, lines 28-49).

Regarding Claim 9, Lipshutz et al disclose the detection cell wherein the membrane comprises a flat sheet (Column 17, lines 28-49 and Fig. 2B, #120).

Regarding Claim 10, Lipshutz et al disclose the detection cell comprising a filtrate chamber (i.e. separation chamber) mated to said sample chamber via said membrane (Column 30, lines 15-28).

Regarding Claim 11, Lipshutz et al disclose the detection cell further comprising a lower flat plate coupled to the upper flat plate and forming a filtrate chamber, wherein the membrane is mounted between the lower flat plate and the upper flat plate, such that the sample chamber and the filtrate chamber are separated by the membrane (Column 17, lines 28-49 and Fig. 2B).

Regarding Claim 12, Lipshutz et al disclose the detection cell wherein the lower flat plate includes a second optical window capable of transmitting light between the filtrate

chamber and a detector for monitoring the filtrate chamber i.e. the lower plate is made of glass (Column 15, lines 26-29).

Regarding Claim 13, Lipshutz et al disclose the detection cell wherein the filtrate chamber is offset from the sample chamber i.e. the detection cell comprises multiple reaction chambers offset from each other e.g. the sample collection chamber, nucleic acid extraction chamber and amplification chamber into which filtrate from the nucleic acid extraction chamber is transferred for amplification (Column 18, lines 5-67 and fig. 3).

Regarding Claim 16, Lipshutz et al disclose detection cell wherein the membrane has a molecular cut-off such that a labeled nucleotide excision product passes through the membrane i.e. the membrane is porous to restrict material passage (Column 22, lines 44-48).

Regarding Claim 29, Lipshutz et al disclose a system for detecting the presence of a nucleotide sequence in a DNA sample comprising: a flat plate detection cell having an interior chamber, a membrane provided along a portion of the interior chamber (Column 17, lines 28-49 and Fig. 2B, #120) and an optical window providing access to the interior chamber (Column 19, lines 20-29); and an optical detector positioned relative to the optical window to monitor the interior chamber (Column 11, lines 43-52; Column 13, lines 25-46; and Fig. 1).

Regarding Claim 30, Lipshutz et al disclose the system wherein the interior chamber comprises a sample chamber holding a biological sample, and the optical detector monitors the biological sample (Column 11, lines 43-52; Column 13, lines 25-46; Column 30, lines 15-24; and Fig. 1).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) in view of Brattesani (U.S. Patent No. 5,743,887, issued 28 April 1998).

Regarding Claims 2-3, Lipshutz et al disclose a flat plate nucleotide detection cell, comprising: an upper flat plate, a sample chamber formed along a bottom surface of said upper flat plate for holding a sample (i.e. planar member); a membrane provided along a portion of said sample chamber for separating a sample in the sample chamber (Column 17, lines 28-49), and an optical window provided in said upper flat plate (Column 14, line 12-Column 15, line 28 and Column 19, lines 20-29), said optical window for permitting light to pass between the sample chamber and a detector for monitoring the sample chamber (Column 4, lines 16-21). Lipshutz et al teach the detection cell wherein the sample is injected using a syringe (Column 24, lines 15-18) and through a sealable opening (i.e. sealed after fluid introduction, Column 20, lines 37-46) but they do not teach the specific structure of a syringe docking port. However, syringe docking ports and guides were well known in the art of syringe injection as taught by Brattesani who specifically teach that syringe docking ports and guides protect persons using the syringe from needle puncture (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the syringe docking and guides of Brattesani to the detection cell of Lipshutz et al and to provide their detection cell with syringe docking port and guide to thereby protect the person using the syringe from needled puncture as taught by Brattesani (Abstract).

Regarding Claim 4, Lipshutz et al teach the detection cell wherein following sample introduction a fluid-tight seal is provided (Column 20, lines 37-46)..

Regarding Claim 5, Lipshutz et al teach the detection cell wherein the sample is injected into the cell such that the needled does not enter the sample chamber i.e. the sample is injected via a sealable opening adjacent to the sample chamber (Fig. 5A, #502).

Regarding Claims 6-7, Lipshutz et al does not specifically teach a needled guide. However, they do illustrate an opening for sample injection (Fig. 5A, #502) and Brattesani teach that needle guides are funnel shaped and protect the user from needle puncture (Abstract and Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the funnel shaped needle guide of Brattesani to the inject port of Lipshutz et al to thereby protect the user from needle puncture as taught by Brattesani (Abstract).

6. Claims 17 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999).

Regarding Claim 17, Lipshutz et al disclose a flat plate nucleotide detection cell, comprising: an upper flat plate, at least one sample chamber formed along a bottom surface of said upper flat plate (i.e. planar member); a lower flat plate forming a filtrate chamber; a membrane provided along a portion of said sample chamber for separating a sample in the sample chamber (Column 17, lines 28-49), and an optical window provided in said upper flat plate (Column 14, line 12-Column 15, line 28; Column 19, lines 20-29; Column 22, lines 19-48 and Fig. 6), said optical window for permitting light to pass between the sample chamber and a

detector for monitoring the sample chamber (Column 4, lines 16-21) wherein the optical detector monitors one or more operations of the device (Column 10,lines 29-34) which clearly suggest that filtrate is monitored but they do not specifically teach that the optical detector monitors the filtrate. However, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to monitor the filtrate as suggested by Lipshutz et al to thereby insure that sample of interest is not being filtered from the sample cell. For example, if the detection cell is used for DNA hybridization whereby labeled targets are hybridized to immobilized probes and if labeled probes were being filtered out of the cell before or during hybridization this would indicate that the hybridization cell was not functioning properly and results obtained from the cell would be inaccurate. In this situation, one of ordinary skill in the art would be motivated to monitor the filtrate to insure that labeled targets were not being filtered from the detection cell because labeled target in the filtrate would indicate that the hybridization results were inaccurate.

Regarding Claim 31, Lipshutz et al teach the system wherein the interior chamber comprises a filtrate chamber for collecting a filtrate from the membrane (Column 30, lines 15-28) wherein the optical detector monitors one or more operations of the device (Column 10,lines 29-34) which clearly suggest that filtrate is monitored but they do not specifically teach that the optical detector monitors the filtrate. However, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to monitor the filtrate as suggested by Lipshutz et al to thereby insure that sample of interest is not being filtered from the sample cell. For example, if the detection cell is used for DNA hybridization whereby labeled targets are hybridized to immobilized probes and if labeled probes were being filtered out of the cell before or during hybridization this would indicate that the hybridization cell was not functioning properly and results obtained from the cell would be inaccurate. In this situation, one of ordinary skill in the art would be motivated to monitor the filtrate to

insure that labeled targets were not being filtered from the detection cell because labeled target in the filtrate would indicate that the hybridization results were inaccurate.

7. Claims 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) as applied to Claim 17 above and further in view of Brattesani (U.S. Patent No. 5,743,887, issued 28 April 1998).

Regarding Claims 18-19, Lipshutz et al disclose a flat plate nucleotide detection cell, comprising: an upper flat plate, a sample chamber formed along a bottom surface of said upper flat plate for holding a sample (i.e. planar member); a membrane provided along a portion of said sample chamber for separating a sample in the sample chamber (Column 17, lines 28-49), and an optical window provided in said upper flat plate (Column 14, line 12-Column 15, line 28 and Column 19, lines 20-29), said optical window for permitting light to pass between the sample chamber and a detector for monitoring the sample chamber (Column 4, lines 16-21). Lipshutz et al teach the detection cell wherein the sample is injected using a syringe (Column 24, lines 15-18) and through a sealable opening (i.e. sealed after fluid introduction, Column 20, lines 37-46) but they do not teach the specific structure of a syringe docking port. However, syringe docking ports and guides were well known in the art of syringe injection as taught by Brattesani who specifically teach that syringe docking ports and guides protect persons using the syringe from needle puncture (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the syringe docking and guides of Brattesani to the detection cell of Lipshutz et al and to provide their detection cell with syringe docking port and guide to thereby protect the person using the syringe from needled puncture as taught by Brattesani (Abstract).

Regarding Claim 20, Lipshutz et al teach the detection cell wherein following sample introduction a fluid-tight seal is provided (Column 20, lines 37-46).

Regarding Claim 21, Lipshutz et al teach the detection cell wherein the sample is injected into the cell such that the needled does not enter the sample chamber i.e. the sample is injected via a sealable opening adjacent to the sample chamber (Fig. 5A, #502).

Regarding Claims 22-23, Lipshutz et al does not specifically teach a needled guide. However, they do illustrate an opening for sample injection (Fig. 5A, #502) and Brattesani teach that needle guides are funnel shaped and protect the user from needle puncture (Abstract and Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the funnel shaped needle guide of Brattesani to the inject port of Lipshutz et al to thereby protect the user from needle puncture as taught by Brattesani (Abstract).

Regarding Claim 24, Lipshutz et al disclose the detection cell further comprising a vent hole in fluid communication with the sample chamber providing a vent for the sample chamber (Column 17, lines 28-49).

Regarding Claim 25, Lipshutz et al disclose the detection cell wherein the membrane comprises a flat sheet (Column 17, lines 28-49 and Fig. 2B, #120).

Regarding Claim 26, Lipshutz et al disclose the detection cell wherein the filtrate chamber is offset from the sample chamber i.e. the detection cell comprises multiple reaction chambers offset from each other e.g. the sample collection chamber, nucleic acid extraction chamber and amplification chamber into which filtrate from the nucleic acid extraction chamber is transferred for amplification (Column 18, lines 5-67 and fig. 3).

8. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) in view of Xu et al (Anal. Chem. 1998, 70: 3553-3558).

Regarding Claim 14 and 15, Lipshutz et al teach the detection cell comprising sample chambers which are etched or molded channels (Column 14, line 35-Column 15, line 29) but they do not teach the chambers are serpentine (Claim 14) or S-shaped (Claim 15). However, serpentine and S-shaped sample chambers were well known in the art at the time the claimed invention was made as taught by Xu et al who teach that the serpentine (i.e. S-shaped) sample chambers reduce sample consumption and increase detection sensitivity (page 3554, first paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the sample chambers of Lipshutz et al by etching or molding the chamber into serpentine (i.e. S-shaped) sample chambers as Xu et al for the expected benefit of reducing sample consumption and increasing detection sensitivity as taught by Xu et al (page 3554, first paragraph).

9. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) as applied to Claim 17 above and further in view of Xu et al (Anal. Chem. 1998, 70: 3553-3558).

Regarding Claim 27 and 28, Lipshutz et al teach the detection cell comprising sample chambers which are etched or molded channels (Column 14, line 35-Column 15, line 29) but they do not teach the chambers are serpentine (Claim 27) or S-shaped (Claim 28). However, serpentine and S-shaped sample chambers were well known in the art at the time the claimed invention was made as taught by Xu et al who teach that the serpentine (i.e. S-shaped) sample

chambers reduce sample consumption and increase detection sensitivity (page 3554, first paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the sample chambers of Lipshutz et al by etching or molding the chamber into serpentine (i.e. S-shaped) sample chambers as Xu et al for the expected benefit of reducing sample consumption and increasing detection sensitivity as taught by Xu et al (page 3554, first paragraph).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45-57 of copending Application No. 9/939,520. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims area drawn to a flat plate detection system and differ only in the arrangement of limitations. For example, instant Claim 3 is drawn to a needle stop and needle guide while Claim 1 of the '520 application requires the needle stop and needle guide. The claim sets further differ in that the instant claims require an optical window. However, the '520 specification describes their detection system as

comprising a window i.e. transparent components allowing fluoroscopy (¶ 81). Therefore, the instant claims and the '520 claims are drawn to detection systems comprising the same components and are therefore not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. No claim is allowed.

13. The examiner for this application has changed. Please address future correspondence to BJ Forman, Art Unit: 1634.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
June 11, 2003